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**IN THE UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF ARIZONA**

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|---|---|
| IN RE: Bard IVC Filters Products Liability Litigation,<br><br>DEBRA MULKEY, an individual,<br><br>Plaintiff,<br><br>v.<br><br>C. R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation,<br><br>Defendants. | No. 2:15-MD-02641-DGC<br><br>**DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AS TO PLAINTIFF DEBRA MULKEY'S CLAIMS**<br><br>(Assigned to the Honorable David G. Campbell)<br><br>**(Oral Argument Requested)** |

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**MOTION**

Pursuant to Fed. R. Civ. P. 56, Local Rule 56.1, and Case Management Order No. 23 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move this Court for summary judgment as to Plaintiff Debra Mulkey's product liability claims as alleged in her Short Form Complaint (2:16-cv-00853-DGC, Doc. 1).[1] For the reasons stated below, Bard is entitled to judgment as a matter of law.

This motion is supported by Defendants' Memorandum of Points and Authorities and Separate Statement of Facts ("SSOF") which are filed herewith.

**MEMORANDUM OF POINTS AND AUTHORITIES**

**I. Introduction.**

Plaintiff Debra Mulkey brings this product liability action for damages she claims to have suffered as a result of complications allegedly experienced related to a Bard Eclipse® inferior vena cava ("IVC") filter, a prescription medical device that was placed in her IVC before she underwent bariatric surgery. The subject Eclipse Filter was placed in Ms. Mulkey's IVC on April 11, 2012 (the "Filter"). Plaintiff claims that her Filter is defective because, after placement, it allegedly tilted (among other alleged complications), and she underwent an unsuccessful percutaneous procedure to have the device removed. The Filter remains implanted in Ms. Mulkey. The potential for Ms. Mulkey's Eclipse Filter to tilt and be unable to be retrieved are risks that are well-known and accepted potential complications associated with all retrievable IVC filters, and they are risks that Bard specifically warned about in the Instructions for Use ("IFU") that accompanied Ms. Mulkey's Filter.

Although Plaintiff underwent her unsuccessful removal procedure on October 4,

[1] Plaintiff and Bard have met and conferred regarding the claims that Plaintiff intends to pursue. Plaintiff has agreed that she is not pursuing claims for manufacturing defect (Counts I, V), breach of express warranty (Count X), loss of consortium (Count XV), wrongful death (Count XVI), or survival (Count XVII). However, Plaintiff represented during the meet and confer process that she intends to pursue all of the claims addressed in this Motion.

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2012, she waited until March 29, 2016, to file her lawsuit against Bard, approximately 3 ½ years after her alleged injury and filter complications, and approximately 2 ½ years after the applicable statute of limitations expired.

Bard moves for summary judgment under Federal Rule of Civil Procedure 56 on the following grounds:

A. All of Plaintiff's claims are barred by the 1-year Kentucky statute of limitations.[2]

B. Plaintiff's breach of implied warranty claim (Counts XI) fails as a matter of law because Plaintiff was not in privity with Bard.

C. Plaintiff's failure-to-warn claims (Counts II, VII) fail as a matter of law because Bard provided legally adequate warnings of the complications allegedly experienced by Plaintiff to a learned intermediary (Plaintiff's implanting physician), and any alleged failure to warn by Bard was not the proximate cause of Plaintiff's alleged injuries.

D. Plaintiff's negligent and fraudulent misrepresentation/concealment claims (Counts VIII, XII, XIII) fail as a matter of law because there is no proof that Plaintiff or her implanting physician relied on an alleged misrepresentation or omission of material fact by Bard regarding the Filter.

E. Plaintiff's negligent post-sale duty to warn claim (Count VI) fails as a matter of law because Kentucky does not recognize a post-sale duty to warn.

F. Plaintiff's negligence *per se* claim (Count IX) fails as a matter of law because such a claim cannot be based on alleged violations of federal statutes or regulations.

[2] Although Plaintiff listed the Southern District of West Virginia in Section 7 of her Short Form Complaint, (*see* 2:16-cv-00853-DGC, Doc. 1), Bard and Plaintiff's counsel met and conferred regarding conflict-of-law issues, and the parties agree that Kentucky law applies to Plaintiff's claims. Kentucky has a 1-year statute of limitations. *See* K.R.S. § 413.140(1)(a). Even of West Virginia law applied, that state has a 2-year statute of limitations, *see* W. Va. Code § 55-2-12(a), (b) (2016), and Plaintiff's claims would similarly be time barred.

G. Plaintiff's consumer fraud claim (Count XIV) fails as a matter of law because Plaintiff is not a "purchaser" under the relevant statute, and because the relevant statute applies only to claims based on alleged losses of money or property, not personal injury claims.

**II. Statement of Undisputed Facts.**

Plaintiff Debra Mulkey received a Bard Eclipse Filter on April 11, 2012, before she underwent bariatric surgery. (SSOF ¶ 1.) The Filter is not sold directly to patients. (*Id.* at ¶ 2.) Ms. Mulkey's implanting physician, Dr. Roderick Tompkins, testified that he placed the Filter in Plaintiff because [redacted] (*Id.* at ¶ 3.) At the time Plaintiff received her Filter, [redacted] (*Id.* at ¶ 4.)

Dr. Tompkins testified that before he placed the Filter, he had the IFU that accompanied the Filter available to him to read. (*Id.* at ¶ 5.) The relevant IFU contains specific warnings regarding the risks of filter tilt, migration, perforation, fracture, and inability to retrieve. (*Id.* at ¶ 6.) Dr. Tompkins testified that he discussed with Ms. Mulkey the risks and benefits of IVC filter placement, and then obtained her informed consent before placing the Filter. (*Id.* at ¶ 12.) Notably, complications such as tilt, migration, perforation, fracture, and inability to retrieve are complications associated with all brands of retrievable IVC filters, not just Bard's IVC filters. Indeed, even Plaintiff's expert acknowledges that all IVC filters are known to have complications, including filter fracture, migration, tilt, and perforation. (*Id.* at ¶ 25.)

On May 21, 2012, Ms. Mulkey [redacted] (*Id.* at ¶ 13.) Thereafter, on October 4, 2012, Ms. Mulkey underwent an unsuccessful percutaneous Filter removal procedure with Dr. Pho Nguyen. (*Id.* at ¶ 14.) The operative note from that procedure states that [redacted]

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[redacted] (*Id.* at ¶ 16.) Ms. Mulkey testified that she was "upset" that her filter could not be removed. (*Id.* at ¶ 19.) Furthermore, Ms. Mulkey admits that the first time she experienced symptoms of any bodily injuries related to her Filter was on October 4, 2012, the day of her unsuccessful removal procedure. (*Id.* at ¶ 20.) Even though Plaintiff had knowledge of all of this information, she testified that she never talked to any of her doctors about her IVC filter until December 2016, well after she filed this lawsuit. (*Id.* at ¶ 22.)

Although Dr. Nguyen was unable to remove Plaintiff's Filter, Plaintiff's own vascular and interventional radiologist expert, Dr. Darren Hurst, testified that Ms. Mulkey's Filter could be removed via a complex percutaneous procedure. (*Id.* at ¶ 23.) Likewise, Plaintiff's cardiothoracic surgeon expert, Dr. Derek Muehrcke, testified that Ms. Mulkey's Filter could "likely" be removed via a complex percutaneous procedure. (*Id.* at ¶ 24.) Dr. Hurst also opines that Ms. Mulkey's filter perforated her IVC, caudally migrated, and fractured. (*Id.* at ¶ 26.) Bard's vascular and interventional radiologist expert, Dr. Moni Stein, disputes these opinions. However, in any event, the applicable IFU specifically warned Dr. Tompkins of the potential risks of IVC perforation, caudal migration, and fracture. (*Id.* at ¶ 6.)

## III. Summary Judgment Standard.

Summary judgment is appropriate upon showing that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see Jesinger v. Nev. Fed. Credit Union*, 24 F.3d 1127, 1130 (9th Cir. 1994). "A moving party without the ultimate burden of persuasion at trial . . . has both the initial burden of production and the ultimate burden of persuasion on a motion for summary judgment." *Nissan Fire & Marine Ins. Co. v. Fritz Companies, Inc.*, 210 F.3d 1099, 1102

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(9th Cir. 2000). "In order to carry its burden of production, the moving party must either produce evidence negating an essential element of the nonmoving party's claim or defense or show that the nonmoving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial." *Id.* "If . . . a moving party carries its burden of production, the nonmoving party must produce evidence to support its claim or defense. If the nonmoving party fails to produce enough evidence to create a genuine issue of material fact, the moving party wins the motion for summary judgment." *Id.* at 1130-31 (internal citations omitted).

## IV. Argument and Citation of Authority.

### A. Plaintiff's Claims Are Barred by Kentucky's One-Year Statute of Limitations.

Plaintiff waited approximately 3 ½ years after her unsuccessful removal procedure to bring this lawsuit against Bard. Kentucky has a 1-year statute of limitations for personal injury product liability actions. *See* K.R.S. § 413.140(1)(a) (providing that "action for an injury to the person of the plaintiff" is one that must "be commenced within one (1) year after the cause of action accrued"). Notably, the limitations period begins running "on the date the injury is inflicted even where the injury is slight initially and its full extent is not known until years later." *Asher v. Unarco Material Handling, Inc.*, 596 F.3d 313, 321–22 (6th Cir. 2010) (applying Kentucky law); *see also Caudill v. Arnett*, 481 S.W.2d 668, 669 (Ky. 1972) (holding that the statute of limitations began running when the plaintiff sustained "minor" injuries while riding a school bus that overturned, not when he was diagnosed more than six years later with chronic pancreatitis caused by the accident).

Although Kentucky recognizes the "discovery rule," that rule "is available ***only*** in cases where the fact of injury or offending instrumentality is not immediately evident or discoverable with the exercise of reasonable diligence, such as in cases of medical malpractice or latent injuries or illnesses." *Fluke Corp. v. LeMaster*, 306 S.W.3d 55, 60 (Ky. 2010) (emphasis added). Thus, where a plaintiff knows or with the exercise of reasonable diligence should know "the fact of injury" or "offending instrumentality," the

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discovery rule does not apply. *See id.* Furthermore, "plaintiffs have a duty to inquire into the safety of products where it is apparent from the facts that the product may have been a potential cause of an injury." *Id.* Accordingly, "[a]n injured party has an affirmative duty to use diligence in discovering the cause of action within the limitations period. Any fact that should excite his suspicion is the same as actual knowledge of this entire claim." *Id.* at 64 (internal quotation marks omitted).

Pursuant to Kentucky's 1-year statute of limitations, Plaintiff's claims are time barred as a matter of law. Specifically, as of October 4, 2012, Plaintiff knew or should have known "the fact of injury." *Id.* at 60. Indeed, Plaintiff admits that she understood Dr. Nguyen "was having some problems" trying to remove her Filter, that the Filter "had grown into the vein," that further attempts to remove the Filter could "caus[e] too much damage to my vein," and that, as a result, Dr. Nguyen would be unable to retrieve her Filter. (SSOF, ¶ 16.) She testified that "it upset me when I found out it [the Filter] couldn't be removed." (*Id.* at ¶ 19.) She also admits that the first time she experienced symptoms of any "bodily injuries" related to her Filter was on October 4, 2012, the day of her unsuccessful removal procedure. (*Id.* at ¶ 20.) Notwithstanding having this information as of October 4, 2012, Plaintiff testified that she never talked to any of her doctors about her IVC filter until December 2016, well after she filed the instant lawsuit. (*Id.* at ¶ 22.) Pursuant to the rule stated by the Kentucky Supreme Court in *LeMaster*, because the "fact of injury" ***was*** "immediately evident or discoverable with the exercise of reasonable diligence" to Plaintiff, *see LeMaster*, 306 S.W.3d at 60, the discovery rule simply does not apply in Plaintiff's case. *See id.* (holding that the discovery rule only applies "where the fact of injury or offending instrumentality is not immediately evident or discoverable with the exercise of reasonable diligence").

Plaintiff may argue that the discovery rule should apply because she claims she did not first attribute her bodily injuries to her Filter until October 2015 when she "saw a commercial on TV that indicated that IVC filters were causing bodily injuries to people." (SSOF, at ¶ 21.) However, seeing a television advertisement paid for by Plaintiffs'



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attorneys seeking new personal injury plaintiffs is not the type of event that triggers a statute of limitations under Kentucky law. Indeed, United District Court Chief Judge Clay Land, who is overseeing the multidistrict litigation *In re Mentor Corp. Obtape Transobturator Sling Products Liability Litigation*, which is pending in the Middle District of Georgia, addressed a similar issue under Kentucky law last year. There, the plaintiff received an ObTape implant in January 2005. *See In re Mentor Corp. Obtape Transobturator Sling Prod. Liab. Litig.*, No. 2004408MD2004CDL, 2016 WL 873647, at *1 (M.D. Ga. Mar. 4, 2016) (applying Kentucky law). Later in 2005, she experienced dyspareunia and an infection, and underwent two revision surgeries. *See id.* However, she waited until 2012 to file her claim against the manufacturer of the ObTape. In responding to the manufacturer's motion for summary judgment, the plaintiff argued that Kentucky's 1-year statute of limitation should not preclude her claim because she did not learn of the alleged connection between her ObTape and her injuries until after learning of a television commercial regarding mesh complications. *See id.* at 2. The MDL court rejected the argument. It reasoned that by the end of 2005, the plaintiff had undergone two revision surgeries for infections, and she "presented no evidence that her doctors told her that her injuries were ***not*** connected to ObTape." *Id.* (emphasis in original). Thus, the court reasoned that "by December 2005, [the plaintiff] had enough information to know of a connection between ObTape and at least some of her injuries. A reasonable person in that situation would take some action to follow up on the cause of her injuries and try to find out whether the injuries were caused by a problem with ObTape, a problem with the implant surgery, or some other problem." *Id.* Finally, the MDL court stated that the plaintiff "reasonably should have suspected a connection between ObTape and her injuries, so she had a duty to investigate. She did not, so the discovery rule does not save her claims." *Id.*

Like the plaintiff in the *ObTape* case above, Plaintiff here had sufficient information on October 4, 2012 -- the day of her unsuccessful removal procedure -- to put her on notice such that a reasonable person would follow-up and investigate the potential

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cause of her injuries. Indeed, Plaintiff admits that, as of October 4, 2012, (a) she first experienced symptoms of "bodily injuries" that she claims resulted from her Filter; (b) that Dr. Nguyen "was having some problems" trying to remove her Filter; (c) that her Filter "had grown into [her] vein"; (d) that further attempts to remove her filter could "caus[e] too much damage to my vein"; (e) that there was "some reason" why Dr. Nguyen could not remove her Filter (even if she did not subjectively know the precise reason); (f) that she knew she did not need her filter anymore; and (g) that she was "upset" that her Filter could not be removed. (SSOF, at ¶¶ 16, 17, 18, 19, 20.) At the very least, Plaintiff had sufficient facts to "inquire into the safety of [her Filter]" to determine whether the "product may have been a potential cause of an injury." *LeMaster*, 306 S.W.3d at 60. That is, the facts known to her were sufficient to the point that they "should [have] excite[d] [her] suspicion" such that she should be charged with "actual knowledge of this entire claim." *Id.* at 64. Moreover, like the plaintiff in the *ObTape* case above, Plaintiff has presented no evidence that her doctors told her that her injuries were not connected to her Filter. Finally, like the above plaintiff, Plaintiff here did absolutely no investigation until after learning of television commercials regarding alleged defects with her Filter.

Because Plaintiff failed to file her lawsuit against Bard within the 1-year statute of limitations, and because the discovery rule does not apply to Plaintiff's claims, Bard respectfully asks this Court to grant summary judgment as to all of Plaintiff's claims.

**B. Plaintiff's Breach of Implied Warranty Claim (Counts XI) Fails as a Matter of Law Because Plaintiff Was Not in Privity with Bard.**

Under Kentucky law, privity of contract is required for a plaintiff to bring an action based on breach of implied warranty. *See, e.g., Brown Sprinkler Corp. v. Plumbers Supply Co.*, 265 S.W.3d 237, 240 (Ky. Ct. App. 2007) ("[A] plaintiff-buyer asserting a claim based upon an implied warranty *must establish* that it enjoyed privity of contract with the defendant-seller against whom the implied warranty claim is asserted.") (emphasis in original); *Compex Int'l Co. v. Taylor*, 209 S.W.3d 462, 465 (Ky. 2006) (noting vertical privity is a requirement for a plaintiff to maintain a breach of warranty action); *Baird v.*

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*Bayer Healthcare Pharm., Inc.*, No. CIV.A. 6:13-077-DCR, 2013 WL 5890253, at *3 (E.D. Ky. Oct. 31, 2013) ("As this Court has previously noted, privity of contract is an essential element to breach of warranty claims."). Privity of contract requires "an underlying contractual relationship," one existing in a "buyer-seller relationship." *Compex*, 209 S.W.3d at 465. Kentucky courts have defined the privity of contract requirement to mean that "a 'seller's' warranty protections are *only* afforded to 'his buyer.'" *Id.* (emphasis in original).

Here, Plaintiff was never in privity with Bard, as the Filter is a prescription medical device that is not sold directly to patients. (SSOF, ¶ 2.) Plaintiff can produce no evidence that she is a "buyer" of the Filter from Bard. Consequently, Bard is entitled to summary judgment on Plaintiff's breach of implied warranty claim. *See Allen v. Abbott Labs.*, No. CIV.A. 11-146-DLB, 2012 WL 10508, at *6 (E.D. Ky. Jan. 3, 2012) (granting the defendant's motion for summary judgment on the plaintiff's breach of warranty claims, where the plaintiff failed to produce evidence of privity of contract in a prescription pharmaceutical drug case).

**C. Plaintiff's Failure-to-Warn Claims (Counts II, VII) Fail as a Matter of Law Because Bard Provided Legally Adequate Warnings to a Learned Intermediary, and Any Alleged Failure to Warn Was Not the Proximate Cause of Plaintiff's Alleged Injuries.**

Plaintiff's failure-to-warn claims fail because Bard provided legally adequate warnings of the complications allegedly experienced by Plaintiff to a learned intermediary, Plaintiff's implanting physician, Dr. Tompkins. Moreover, any alleged failure to warn by Bard was not the proximate cause of Plaintiff's alleged injuries.

Under Kentucky law, for a failure-to-warn claim, "liability for a manufacturer follows only if it knew or should have known of the inherent dangerousness of the product and failed to 'accompany [ ] it with the quantum of warning which would be calculated to adequately guard against the inherent danger.'" *CertainTeed Corp. v. Dexter*, 330 S.W.3d 64, 79 (Ky. 2010) (alteration in original) (quoting *Post v. Am. Cleaning Equip. Corp.*, 437 S.W.2d 516, 520 (Ky. 1968)). As with other claims, to succeed on a failure-to-warn claim,

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a plaintiff has the burden of establishing causation. *See Morales v. Am. Honda Motor Co.*, 71 F.3d 531, 537 (6th Cir. 1995) (applying Kentucky law). "[U]nder Kentucky law, causation or proximate cause is defined by the substantial factor test: was the defendant's conduct a substantial factor in bringing about plaintiff's harm?" *Id.* (citing *Deutsch v. Shein*, 597 S.W.2d 141, 144 (Ky. 1980)). "Causation is an element which may be proved by circumstantial evidence, and in that situation 'the evidence must be sufficient to tilt the balance from possibility to probability.'" *Morales*, 71 F.3d at 537 (quoting *Calhoun v. Honda Motor Co., Ltd.*, 738 F.2d 126, 130 (6th Cir. 1984)). In other words, a plaintiff has the burden of producing evidence to justify a reasonable inference of ***probability rather than a mere possibility***. *See Holbrook v. Rose*, 458 S.W.2d 155, 158 (Ky. 1970) ("[T]he essence of the test concerning the sufficiency of plaintiff's circumstantial evidence concerning causation is that the proof must be sufficient to tilt the balance from 'possibility' to 'probability.'").

In 2004, the Supreme Court of Kentucky adopted the learned intermediary rule. *See Larkin v. Pfizer*, 153 S.W. 3d 758 (Ky. 2004). Under the learned intermediary rule, a manufacturer of a prescription drug or medical device discharges its duty to warn if it provides a legally adequate warning to the "learned intermediary," which is the prescribing physician. *See id.* at 764. Stated differently, "[t]he obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider's prescription traditionally has required warnings directed to health-care providers and not to patients." *Id.* at 762 (quoting *Restatement (Third) of Torts: Prods. Liab.* § 2 cmt. I)). Courts applying Kentucky law have applied the learned intermediary rule to prescription pharmaceutical drugs and medical devices. *See, e.g.*, *Larkin*, 153 S.W.3d 758 (prescription drugs); *Whybark v. Synthes, Inc.*, No. 515CV00084GNSLLK, 2017 WL 1788673, at *3 (W.D. Ky. May 4, 2017) (medical devices).

Here, the Filter is a prescription medical device not available to the general public. (SSOF, ¶ 2.) Accordingly, the learned intermediary doctrine applies, and Bard only had a

duty to warn Dr. Tompkins, the physician who implanted the Filter, of the risks of its use. Dr. Tompkins' testimony establishes that the warnings accompanying the Filter were adequate to warn him of the specific complications encountered by Ms. Mulkey. Dr. Tompkins testified that before he placed the Filter, he had the IFU that accompanied the Filter available to him to read. (*Id.* at ¶ 5.) The relevant IFU contains specific warnings regarding the risks of filter tilt, migration, fracture, perforation, and inability to retrieve, which are complications allegedly experienced by Ms. Mulkey. (*Id.* at ¶ 6.) Under the bolded heading "**Potential Complications**," the IFU reads as follows:

> - Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. . . .
>
> - Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
>
> - Perforation or other acute or chronic damage of the IVC wall.
>
> * * *
>
> - Filter Tilt
>
> * * *
>
> **All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ration for a patient who is at risk of pulmonary embolism without intervention.**

(*Id.* at ¶ 6.a) (emphasis in original). Additionally, under the bolded "**Eclipse Filter Removal**" heading, the IFU states in bolded language as follows:

> **It is possible that complications such as those described in the "Warnings", "Precautions," or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted**.



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(*Id.* at ¶ 6.b) (emphasis in original). Because the IFU warned Dr. Tompkins regarding the relevant risks of using the Filter, Bard's warnings were legally adequate. *See CertainTeed Corp. v. Dexter*, 330 S.W.3d 64, 79 (Ky. 2010) (holding that if product includes inherent dangers, manufacturer must provide "'quantum of warning which would be calculated to adequately guard against the inherent danger'" (quoting *Post v. Am. Cleaning Equip. Corp.*, 437 S.W.2d 516, 520 (Ky. 1968))).[3]

In addition, Plaintiff has not established that any failure to warn by Bard was the proximate cause of her injuries. Although Dr. Tompkins testified on occasion that he would have "wanted to know" certain alleged factual information presented by Plaintiff's counsel, he admitted that he would be ***speculating*** as to whether such information would have altered his treatment decision for Plaintiff. (SSOF, ¶ 7.) Specifically, he testified as follows:

> 13 Q And it's important for you to rely on
> 14 accurate or reliable information, isn't that
> 14 right --
> 16 A Yes.
> 15 Q -- in making a decision as a medical
> 18 doctor?
> 16 A Yes.
> 20 Q Okay. So -- so again, being shown a
> 17 draft e-mail and asked if you had known, if you
> 22 had known, would you have made a different
> 18 decision, ***you're really speculating, aren't you***?
> 24 MR. DeGREEFF: Object to the form.
> 19 A ***Yes***.
> 1 Q Doctor, would you need much more
> 20 2 information other than an e-mail or a couple of
> 3 documents provided to you with testimony by
> 21 4 counsel in making a decision whether you would use
> 5 a product or not?

[3] Plaintiff may argue that Bard failed to warn Dr. Tompkins regarding the relative complication rates of Bard's IVC filters compared to competitor devices. Such an argument would be misplaced. Under Kentucky law, a manufacturer's obligation is to warn "of non-obvious dangers inherent in the probable use ***of the product***," not to provide a warning regarding some other product or products. *See Tipton v. Michelin Tire Co.*, 101 F.3d 1145, 1150 (6th Cir. 1996) (emphasis added). Accordingly, for the reasons and arguments stated at footnote 3, page 9 of Bard's Motion for Summary Judgment filed in *Jones v. C. R. Bard, Inc., et al.*, which are incorporated herein by reference, Bard had no legal duty to provide warnings to Dr. Tompkins regarding the rates of complications with the Eclipse Filter in comparison to any other product.



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* * *

8 A Can you restate that?
9 Q Sure.
10 Would you need information beyond
11 documents taken out of context -- internal
12 documents taken out of context to make a decision
13 as to whether you would use a product or not?
14 MR. DeGREEFF: Object to form. Same
15 objection.
16 A Yes.

(*Id.* at ¶ 7) (emphasis added).

Critically, Dr. Tompkins never testifies that had he been given different information about the Eclipse Filter, it is probable that he would have decided against using the device. (*Id.* at ¶ 8.) In the absence of evidence establishing that an alleged failure to warn was the "probable" cause of Plaintiff's injury -- that is, that a different warning would have probably caused Dr. Tompkins to choose a different product -- Bard is entitled to summary judgment on Plaintiff's failure-to-warn claims. *See, e.g., Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (noting that a plaintiff has the burden to prove that "a proper warning would have changed the decision of the treating physician, *i.e.* that *but for* the inadequate warning, the treating physician would not have used or prescribed the product"); *Ingram v. Novartis Pharm. Corp.*, 888 F. Supp. 2d 1241, 1246–47 (W.D. Okla. 2012) (granting summary judgment to defendant in prescription drug case, where plaintiff failed to produce evidence that treating physician would have changed treatment decision had a proper warning been given); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 995 (C.D. Cal. 2001) ("Pfizer may prevail in its motion for summary judgment if Ms. Motus has failed to adduce evidence that Dr. Trostler would have acted differently had Pfizer provided an adequate warning.").

**D. Plaintiff's Negligent and Fraudulent Misrepresentation/Concealment Claims (Counts VIII, XII, XIII) Fail as a Matter of Law Because Plaintiff Cannot Prove the Essential Elements of Reliance or Inducement.**

To establish a claim of negligent or fraudulent misrepresentation, a plaintiff has the burden to prove that he or she "acted in reliance" upon an alleged "material

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misrepresentation." *See, e.g.*, *Denzik v. Denzik*, 197 S.W.3d 108, 110 (Ky. 2006).[4] Similarly, to succeed on a fraudulent concealment claim (also called fraud by omission), a plaintiff must prove that "the defendants' failure to disclose the material fact induced the plaintiff to act." *Rivermont Inn, Inc. v. Bass Hotels & Resorts, Inc.*, 113 S.W.3d 636, 641 (Ky. Ct. App. 2003).

Here, Plaintiff's misrepresentation and concealment claims fail because she cannot prove the essential elements of reliance (for the misrepresentation claims) and inducement (for the concealment claim). Ms. Mulkey testified that she never received a patient card or brochure regarding her IVC filter, nor did she ask for any information about her filter before it was implanted. (SSOF, ¶¶ 27, 28.) Moreover, she has never spoken to anyone at Bard, nor has she visited Bard's website. (*Id.* at ¶ 29, 30.) Indeed, she did not even know that Bard was the manufacturer of her IVC filter until after she contacted her lawyer about her potential legal claim. (*Id.* at ¶ 31.)

Similarly, Plaintiff's implanting physician, Dr. Tompkins, testified that he relied on his experience, the experience of his colleagues, and the applicable medical literature when he decided to implant an Eclipse Filter in Ms. Mulkey. (*Id.* at ¶ 9.) He does not testify that he relied on any statement by Bard -- or on any omission of material fact -- in deciding to use the Filter. To the contrary, he testified that he ***does not*** rely on information from medical device manufacturers, such as Bard, when deciding which IVC filter he wanted to use. Specifically, Dr. Tompkins testified as follows:

> 19 Q So -- so in -- in deciding which --
> 20 which filter to use, do you rely on information
> 21 from the manufacturer?
> 22 A No.

(*Id.* at ¶ 10.) Finally, Dr. Tompkins testified he does not recall discussions with Bard's sales representatives regarding the use of IVC filters in bariatric patients. (*Id.* at ¶ 11.)

[4] "The tort of negligent misrepresentation differs from fraudulent misrepresentation only in that the former tort demands only that a false representation or concealment be made negligently, rather than recklessly or with knowledge of its falsity." *Clark v. Danek Med., Inc.*, 64 F. Supp. 2d 652, 657 (W.D. Ky. 1999).



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Neither Plaintiff nor her implanting physician testified that they relied on a material misrepresentation -- or omission of material fact -- when deciding to use a Bard Eclipse Filter. Because Plaintiff cannot prove the essential elements of reliance or inducement, her misrepresentation and concealment claims fail as a matter of law.

**E. Plaintiff's Negligent Post-Sale Failure to Recall/Retrofit Claim (Count VI) Is Not Recognized by Kentucky Law.**

No Kentucky state court has recognized a post-sale duty to warn. Instead, the Eastern District of Kentucky -- applying Kentucky law and, in particular, Kentucky Supreme Court precedent -- predicted that "Kentucky would not adopt a post-sale failure to warn cause of action." *Cameron v. DaimlerChrysler Corp.*, No. CIV.A. 504CV24JMH, 2005 WL 2674990, at *7 (E.D. Ky. Oct. 20, 2005) (interpreting *Ostendorf v. Clark Equipment Co.*, 122 S.W.3d 530 (Ky. 2003)). The *Cameron* court relied on the Kentucky Supreme Court's refusal in *Ostendorf* to recognize a post-sale duty to retrofit, stating "[b]ecause the [*Ostendorf*] court declined to adopt the duty to retrofit, it is reasonable to assume that the court would similarly reject a post-sale duty to warn for the same reasons. *Cameron*, 2005 WL 2674990, at *7; *see also Ostendorf*, 122 S.W.3d at 533-37 (discussing the court's reasoning for following the majority of jurisdictions in refusing to recognize a post-sale duty to retrofit a product).

Because Kentucky does not recognize a post-sale duty to warn, her negligent failure to recall/retrofit is barred as a matter of law.

**F. Plaintiff's Negligence *Per Se* Claim (Count IX) Fails as a Matter of Law Because it Is Impermissibly Based on Alleged Violations of Federal Statutes or Regulations.**

Although Kentucky recognizes negligence *per se* claims, such a claim may not be based on alleged violations of federal statutes or regulations. *See Young v. Carran*, 289 S.W.3d 586, 589 (Ky. Ct. App. 2008) (holding that Kentucky's negligence *per se* statute, K.R.S. § 446.070, "does not extend to federal statutes and regulations or local ordinances"). As one Kentucky court stated, "[t]he Kentucky General Assembly did not intend for KRS 446.070 to embrace the whole of federal laws and the laws of other states

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and thereby confer a private civil remedy for such a vast array of violations." *T & M Jewelry, Inc. v. Hicks*, 189 S.W.3d 526, 530 (Ky. 2006). Instead, a negligence *per se* claim must be based on alleged violations of a Kentucky statute. *See Young*, 289 S.W.3d at 589.

Plaintiff's negligence *per se* claim (Count IX) is based exclusively on alleged violations of federal statutes and federal regulations. (*See* Master Complaint for Damages for Individual Claims [Dkt. No. 364] at ¶¶ 229-234.) Nowhere in Plaintiff's Master Complaint or Short Form Complaint does Plaintiff identify any alleged violations of Kentucky statutes.[5] Accordingly, her negligence *per se* claim fails as a matter of law.

**G. Plaintiff's Consumer Fraud Claims (Count XIV) Fail as a Matter of Law Because Plaintiff Is Not a "Purchaser" and Because the Relevant Statute Does Not Apply to Personal Injury Claims.**

Kentucky's consumer fraud and unfair and deceptive trade practices statutes are codified under K.R.S. § 367.110, *et seq.* (the Kentucky Consumer Protection Act or "KCPA"). Section 367.220(1) of the KCPA permits a private cause of action if a person suffers an "ascertainable loss of money or property, real or personal" as a result of an unfair or deceptive act of another. To sustain a claim under the KCPA, the plaintiff must be in privity of contract with the defendant. *See Skilcraft Sheetmetal, Inc. v. Kentucky Mach., Inc.*, 836 S.W.2d 907, 909 (Ky. Ct. App. 1992) ("The legislature intended that privity of contract exist between the parties in a suit alleging a violation of the Consumer Protection Act."). A "subsequent purchaser may not maintain an action against a seller with whom he did not deal or who made no warranty for the benefit of the subsequent purchaser." *Id.* "The language of the statute plainly contemplates an action by a purchaser against his immediate seller." *Id.*

As explained in Section A, *supra*, Ms. Mulkey is not in privity of contract with Bard. She is not a "person who purchase[d]" goods under the KCPA. Additionally, Ms.

[5] To the extent Plaintiff claims that her negligence *per se* claim is based on alleged violations of Kentucky's Consumer Protection Act, that claim fails as a matter of law as explained in Section G, *infra*.



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Mulkey's claims are for personal injury damages, not for an "ascertainable loss of money or property" as required under the KCPA. Accordingly, she cannot sustain an action under the KCPA against Bard as a matter of law.[6]

## V. Conclusion.

For these reasons, Bard respectfully requests that this Court grant Bard's Motion for Summary Judgment.

RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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[6] To the extent Plaintiff alleges a violation of the West Virginia Consumer Credit and Protection Act (the "WVCCPA," West Virginia's comparable consumer protection statute), that claim fails as a matter of law as well. The WVCCPA requires that a plaintiff provide pre-suit notice to the seller, and Plaintiff has never provided such pre-suit notice. *See Waters v. Electrolux Home Prod., Inc.*, 154 F. Supp. 3d 340, 354 (N.D.W. Va. 2015) ("Because providing written notice is a prerequisite to filing a complaint, the plaintiffs' complaint cannot have served as the required notice. The plaintiffs failed to plead that they notified Equitrans in writing of the alleged violations prior to filing their complaint. Therefore, their claim under the WVCCPA is barred."). Additionally, like the KCPA, violations of the WVCCPA are predicated on losses of money or property, not personal injury. *See* W.Va. Code 46A-6-106(a). Finally, the WVCCPA applies only to "consumers" under the act, and Plaintiff is not a consumer as that term is defined. W.Va. Code 46A-6-102(2) ("'Consumer' means a natural person to whom a sale or lease is made in a consumer transaction, and a 'consumer transaction' means a sale or lease to a natural person or persons for a personal, family, household or agricultural purpose.").

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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